

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
7 April 2005 (07.04.2005)

PCT

(10) International Publication Number
WO 2005/030177 A2

- (51) International Patent Classification⁷: **A61K 9/20**, 31/66 (74) Agents: **WAIN, Christopher, Paul** et al.; A.A. Thornton & Co., 235 High Holborn, London WC1V 7LE (GB).
- (21) International Application Number:
PCT/GB2004/004146 (81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (22) International Filing Date:
29 September 2004 (29.09.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
1023/MUM/2003
29 September 2003 (29.09.2003) IN (84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- (71) Applicant (*for all designated States except US*): **CIPLA LIMITED** [IN/IN]; 289 Bellasis Road, Mumbai Central, Mumbai 400 008 (IN).
- (71) Applicant (*for MW only*): **WAIN, Christopher, Paul** [GB/GB]; A.A. Thornton & Co., 235 High Holborn, London WC1V 7LE (GB).
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): **LULLA, Amar** [IN/IN]; 131 Maker Towers "L", 13th Floor, Cuffe Parade, Colaba, Mumbai 400 005, Maharashtra (IN). **MALHOTRA, Geena** [IN/IN]; 4 Anderson House, Opposite Mazgaon Post Office, Mazgaon, Mumbai 400 010, Maharashtra (IN).
- Published:
— *without international search report and to be republished upon receipt of that report*
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: PHARMACEUTICAL FORMULATION WITH IMPROVED STABILITY

(57) Abstract: There is provided an oral formulation which includes an intragranular phase comprising a bisphosphonic acid derivative and at least one carbohydrate alcohol, together with an aqueous binder. There is also provide a process of preparing the same and a therapeutic method employing such a formulation in the treatment of various skeletal diseases, such as systemic bone diseases including osteoporosis, osteoarthritis, Paget's disease, osteomalacia, multiple myeloma, and other forms of cancer, steroid therapy wherein the skeletal system is effected and age-related loss of bone mass, local disorders such as bone fractures and other such related disorders.



WO 2005/030177 A2